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Proposed Maximum Residue Limit

PMRL2017-22

Ethylene Oxide

(publié aussi en français)

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Currently, the use of ethylene oxide as a fumigant on spices is enabled under two pieces of legislation, the *Food and Drugs Act* and the *Pest Control Products Act*. Under the *Food and Drugs Act*, there is a food additive provision that permits the use of ethylene oxide at levels consistent with Good Manufacturing Practice on “whole or ground spice (except mixtures containing salt)” provided that residues of ethylene chlorohydrin, a reaction by-product, do not exceed 1500 parts per million (ppm). Ethylene oxide is also currently registered under the *Pest Control Products Act* as a fumigant for use on similar foods, namely on “whole or ground spices and other processed natural seasonings (except mixtures to which salt has been added)”, with the exception of basil.¹

Health Canada considers that the use of ethylene oxide as a fumigant meets the regulatory definition of a pest control product and therefore is appropriately regulated under the *Pest Control Products Act*. Removal of the food additive provision for ethylene oxide will mean that the approved conditions of use of ethylene oxide will reside solely under the *Pest Control Products Act*.

Therefore, Health Canada intends to remove the food additive entry for ethylene oxide, item E.2, from the *List of Permitted Food Additives with Other Generally Accepted Uses*. This modification to the List will result in a single, consistent, appropriate and up-to-date regulatory framework for administering the use of ethylene oxide as a fumigant on spices.

Consultation on the proposed MRLs for ethylene oxide and its degradation product, ethylene chlorohydrin, is being conducted via this document (see Next Steps, the last section of this document). A summary of the field trial data used to support the proposed MRLs can be found in Appendix I.

To comply with Canada’s international trade obligations, consultation on the proposed MRLs is also being conducted internationally by notifying the World Trade Organization, as coordinated by the Canada’s Notification Authority and Enquiry Point.

The proposed MRLs are as follows.

Table 1 Proposed Maximum Residue Limits

Common Name	Residue Definition	MRL (ppm) ¹	Food Commodity
Ethylene oxide	Oxirane	7	Herbs (crop subgroup 19A; dried leaves except dried basil leaves); spices (crop subgroup 19B)

¹ In 2013, as a result of the PMRAs re-evaluation of ethylene oxide, basil may no longer be treated with ethylene oxide, as per the conditions of registration. See: “Re-evaluation Decision RVD2013-02, Ethylene Oxide”

Common Name	Residue Definition	MRL (ppm) ¹	Food Commodity
Ethylene chlorohydrin	2-Chloroethanol	940	Herbs (crop subgroup 19A; dried leaves except dried basil leaves); spices (crop subgroup 19B)

¹ ppm = parts per million

MRLs are proposed for each commodity included in the listed crop groupings in accordance with the Residue Chemistry Crop Groups webpage in the Pesticides and Pest Management section of Health Canada's website.

MRLs established in Canada may be found using the Maximum Residue Limit Database on the Maximum Residue Limits for Pesticides webpage. The database allows users to search for established MRLs, regulated under the *Pest Control Products Act*, both for pesticides or for food commodities.

International Situation and Trade Implications

The MRLs proposed for ethylene oxide and the degradation product, ethylene chlorohydrin, in Canada are the same as corresponding American tolerances as listed in the Electronic Code of Federal Regulations, 40 CFR Part 180, by pesticide. Currently, there are no Codex MRLs² listed for ethylene oxide or the degradation product, ethylene chlorohydrin, in or on any commodity on the Codex Alimentarius Pesticide Residues in Food and Feed webpage.

Next Steps

The PMRA invites the public to submit written comments on the proposed MRLs for ethylene oxide and the degradation product ethylene chlorohydrin up to 75 days from the date of publication of this document. Please forward your comments to Publications (see the contact information on the cover page of this document). The PMRA will consider all comments received before making a final decision on the proposed MRLs. Comments received will be addressed in a separate document linked to this PMRL. The established MRLs will be legally in effect as of the date that they are entered into the Maximum Residue Limit Database.

² The Codex Alimentarius Commission is an international organization under the auspices of the United Nations that develops international food standards, including MRLs.

Appendix I

Summary of Field Trial Data Used to Support the Proposed Maximum Residue Limits

Residue data from fumigation trials conducted in the United States were submitted to support the continued registration of Ethylene Oxide Fumigant Sterilant (*Pest Control Products Act* Registration Number 22965) on dried herbs (except dried basil leaves) and spices. Ethylene oxide was applied to several dried herbs and spices at rates within the registered rate, and collected according to label directions.

Maximum Residue Limits

The recommendation for maximum residue limits (MRLs) for ethylene oxide and its degradation product ethylene chlorohydrin was based upon the submitted fumigation trial data, and the guidance provided in the OECD MRL Calculator. Table A1 summarizes the residue data used to calculate the proposed MRL(s) for dried herbs (except dried basil leaves) and spices.

Table A1 Summary of Field Trial and Processing Data Used to Support MRLs

Analyte	Application Method/ Total Application Rate (mg a.i./L) / Duration ¹	Post-treatment Interval (hours)	Lowest Average Field Trial Residues ² (ppm)	Highest Average Field Trial Residues ² (ppm)	Experimental Processing Factor
ethylene oxide	Fumigation / 300 / 6 hours	24	1.0	3.34	None
ethylene chlorohydrin		24	13	854	

¹ mg a.i./L = milligrams of active ingredient per litre

² The residues reported are from all the trials conducted on dried herbs and spices

Following the review of all available data, MRLs as proposed in Table 1 are recommended to cover residues of ethylene oxide and its degradation product ethylene chlorohydrin. Residues of ethylene oxide and its degradation product ethylene chlorohydrin in these commodities at the proposed MRLs will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.